WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/EP2004/010983

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this opinion is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

   Description, Pages

   1-25 as originally filed

   Claims, Numbers

   1-15 received on 03.08.2005 with letter of 02.08.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-15

because:

☒ the said international application, or the said claims Nos. 7 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-15 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search opinion has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See supplemental sheet for further details

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/EP2004/010983

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-15
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6,8-15
	No:	Claims	

2. Citations and explanations:

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY (SEPARATE SHEET)

International application No. PCT/EP2004/010983

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 7 relates to a method of improving the immunity of a non-human animal. Due to:
a) the reference in page 7, lines 4-5 to the effect of the claimed composition in reducing the death rate of said animals caused by **diseases**,
b) example 5 referring to the treatment of piglets having a Staphylococcus infection,
c) claim 8 referring to "**therapeutical** compositions for stimulating the immune system" and
d) claim 12 referring to "animals having a growth deficit and/or weakened immune system" thus to non-healthy animals,
claim 7 is considered to have a therapeutical aspect and thus its subject-matter is considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).
Claim 7 could be considered as a non-"method of treatment"-claim, only in the case that it was clear, that this method were to be applied in healthy animals.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: PATENT ABSTRACTS OF JAPAN vol. 2003, no. 02, 5 February 2003 (2003-02-05) & JP 2002 281914 A (NISHI NIPPON GREEN KK), 2 October 2002 (2002-10-02)

D2: PATENT ABSTRACTS OF JAPAN vol. 009, no. 331 (C-321), 25 December 1985 (1985-12-25) & JP 60 161920 A (MASAKI KAMATA), 23 August 1985 (1985-08-23)

D3: PATENT ABSTRACTS OF JAPAN vol. 010, no. 056 (C-331), 6 March 1986 (1986-03-06) & JP 60 199801 A (MASAKI KAMATA), 9 October 1985 (1985-10-09)

D4: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 16, 8 May 2001 (2001-05-08) & JP 2001 026579 A (KOBE TENNENBUTSU KAGAKU KK; JAPAN SCIENCE & TECHNOLOGY CORP), 30 January 2001 (2001-01-30)

The application refers to an **animal feed composition** comprising free **IAA** or a derivative thereof capable of stimulating growth or the immune system in animals.

1) Article 33(2) PCT

Document D1 refers to a method for producing nutrient vitality promoter for fishes and livestock comprising indoleacetic acid. D2 refers to a growth agent for animal containing a plant growth hormone eg. oxyauxin such as oxyindoleacetic acid. D3 discloses a method for administering plant growth hormone eg. auxin (IAA) to an animal.

However, a minimum quantity of 240 microgram of IAA or a derivative thereof per kilogram of feed composition is not disclosed in any of these documents. The subject matter of the present application can thus be considered to fulfill the requirements of Article 33(2) PCT.

2) Article 33(3) PCT

The technical problem underlying the present application is the provision of an animal feed composition capable of increasing the growth rate and/or improving the feed efficiency and/or the feed conversion rate and/or the immunity of an animal. It is also directly claimed the use of IAA or a derivative thereof for the preparation of a therapeutical composition for stimulating the immune system of non-human animals (claim 8).

Although the prior art disclosed the use indoleacetic acid for enhancing growth in animals as well as its nutritional aspect (D1), there was no indication for the stimulating aspect of IAA or a derivative thereof on the immune system of the animals.

The subject matter of the present application can thus be acknowledged as inventive according to Article 33(3) PCT.

3) Article 34(4)(a)(I) PCT / Rule 67.1(iv) PCT

For the assessment of the present claim 7 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VII

Certain defects in the international application

a) The relevant background art disclosed in the documents D1-D3 is missing from the description (Rule 5.1(a)(ii) PCT).

b) The formulation of claim 9 corresponds to a second medical use claim. However, the stimulation of growth can not be considered as a therapeutical application.

Re Item VIII

Certain observations on the international application

1) Claim 1 and subsequently following claims referring to claim 1, do not fulfill the requirements of Article 6 PCT:

a) Claim 1 is an "open-ended claim". Although the minimum concentration of IAA or a derivative thereof is defined, no reference is made in claim 1 regarding its maximum concentration. Such a reference is only to be found in the dependent claim 2. Subsequently, claim 1 may refer to concentrations more than 40g of free IAA or a derivative thereof, such as eg. 999g. For such high concentrations it is however questionable if the technical problem can be solved (Article 33(3) PCT).

b) The essential feature of the claimed feed compositions is a minimum concentration of free IAA or a derivative thereof of 240 microgram per kilogram. This is also the feature that differentiates the present application from the prior art. However, 240 microgram of a derivative of IAA would lead -after conversion- to a lower quantity of IAA.

c) The definition of the derivative as "a compound that can be converted into free IAA in 3, preferably in 2 and more preferably in 1 step":

I) is a functional definition

ii) it does not make clear which compounds are covered by the scope of the claim. The reference to Bartel et al. is not sufficient as to clarify which compounds are meant. For example, according to Bartel et al. indole is converted in at least 4 steps to IAA. In D4, however, indole is converted in 3 steps to IAA. It is therefore not clear if indole will be comprised within the scope of the claim.

iii) the wording "preferably" has no limiting effect on the scope of the claims. The features following these expressions are therefore superfluous, thereby resulting in a lack of conciseness of the claim.

2) The concentration of free IAA or a derivative of 240 microgram till 40 gram per kilogram may be considered as broad for the claimed effect.

3) The reference in claim 4 to "an enzyme capable of converting the derivative into free IAA" is objected under Article 6 PCT.

4) Claim 5 can not be considered as clear. In the originally filed claims this claim was referring to the aromatic ring of 4-hydroxy-IAA etc.. However in the amended set of claims this reference point is missing, while the dependancy on claim 4 is considered as incorrect.

5) As mentioned under Point VII, the formulation of claim 9 corresponds to a second medical use claim. However, the stimulation of growth can not be considered as a therapeutical application.

6) Claim 10 is a "result-to-be-achieved" claim.

7) Claim 15 referring to a "method of raising non-human animals" is objected under Article 6 PCT.

8) The reference to "animal" in claims 9-15 includes also human beings.

The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.
Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).
If the applicant regards it as appropriate these indications could be submitted in handwritten

form on a copy of the relevant parts of the application as filed.
Also any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).